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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,003	10/30/2003	Itzhak Bentwich	050992.0300.10USCP	1002

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ROSETTA-GENOMICS
c/o PSWS
700 W. 47TH STREET
SUITE 1000
KANSAS CITY, MO 64112

EXAMINER	
SHIN, DANA H	
ART UNIT	**PAPER NUMBER**
1635	

MAIL DATE	DELIVERY MODE
11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/707,003	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8-10-07 and 10-11-07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 11, 2007 has been entered.

Status of Claims

No new claim amendments have been filed with the request for continued examination under 37 CFR 1.114. Accordingly, amendments to the claims filed on August 10, 2007 containing claims 21-23 and 32-36 are currently under examination on the merits.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/457,788, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application, because the instantly claimed 70.9%, 79.2%, and 83.4% were not disclosed. The disclosure of the claimed SEQ ID NO:3588 in 60/457,788 is acknowledged per applicant's submission of Appendix A filed on October 11, 2007. Since the instantly claimed sequence identity levels are not adequately described in 60/457,788, the benefit of the priority to Application No. 60/457,788 is denied and the instant filing date, October 30, 2003, will be the effective filing date for the instant case.

If applicant believes that the instantly claimed nucleic acid molecules as a whole are adequately described and supported in the provisional application in the manner provided by the first paragraph of 35 U.S.C. 112, applicant is advised to point out the particulars in response to this Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-23 and 32-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification expressly teaches that the novel genes are micro RNA-like regulatory genes, which modulate expression of known host target. See paragraph 0062. The specification merely indicates that the claimed "isolated nucleic acid" ***may*** prove useful without identifying

with specificity why it ***is*** considered useful. See paragraph 0010, which states, "the present invention ***seeks*** to provide improved method and system for detection and prevention of viral disease, which is mediated by this group of novel viral genes." See paragraphs 0137-0141, which describe that the genes of the present invention have a specific, substantial, and credible utility because the detection or therapeutic application of viral miRNAs in clinical scenarios is associated with such utility and because miRNAs modulate expression of disease related target genes. It is known in the art that miRNAs are able to modulate expression of their target genes, as evidenced by the disclosure of the specification. See page 0070. As such, any miRNA has the potential to perform any one of the alleged uses and that nothing about applicant's alleged "uses" distinguish the claim miRNAs from any miRNA known in the art. Applicant's attention is directed to an analogous case law, *In re Fisher,* 421 F.3d at 1374, 76 USPQ2d at 1232, wherein it was found that any EST has the potential to perform any one of the alleged uses and that nothing about applicant's alleged uses distinguish the claimed ESTs from any EST known in the art. The court therefore ruled that the claimed ESTs lack a specific utility: "Accordingly, we conclude that applicant has only disclosed general uses for its claimed ESTs, not specific ones that satisfy §101."

Furthermore, the instantly claimed miRNA SEQ ID NO:3588 is not identified with any target gene or associated with any biological function or any disease. That is, there is no structure/function correlation shown for SEQ ID NO:3588 in the application as filed. Note that applicant stated that the present invention as a substantial utility because the claimed nucleic acid modulates expression of disease related target genes. See paragraphs 0137-0141 in the specification. Since nothing about the claimed nucleic acids is known in the art or taught by the

inventor or disclosed in the instant application, except that they ***could*** be viral microRNAs or RNA-like molecules based on the bioinformatics data, no one skilled in the art would know where to apply or how to use the claimed nucleic acid molecules. As such, the claimed nucleic acid molecules were not understood to the point of providing an immediate, well-defined, real world use to the public. Note that the claimed ESTs in *In re Fisher* were only tools to be used along the way in the "search for a practical utility" but not to be an end of applicant's research effort, because the function of the protein-encoding genes were not identified. Thus, the court ruled that the claimed ESTs lack a substantial utility: "we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent." *Id.* At 1376, 76 USPQ2d at 1233-34.

Since a person of ordinary skill would not immediately recognize a specific and substantial utility for the claimed invention (i.e., why it would be useful) based on the characteristics of the invention, the claimed invention is rejected for lacking a specific and substantial utility.

Applicant must reply by indicating why the invention is believed useful and where support for any subsequently asserted utility can be found in the specification as filed. See MPEP §2701.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-23 and 32-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. See pages 3-5 above.

Claims 21-23 and 32-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, all pending claims have been amended to recite a new limitation of "24 to 120" length parameter and new limitations of 70.9%, 79.2%, and 83.4% sequence identity levels which were not claimed in the application as originally filed. Although the specification adequately describes 50-120 wherein the subsequence is 18-24 in length, the nucleic acid consisting of 20-120 is not adequately described in the specification as filed. Further, there is no adequate written description for the claimed 70.9%, 79.2%, and 83.4% sequence identity levels in the specification as originally filed. Since applicant has not pointed out where amended claims are supported, nor does there appear to be a written description of the claim limitations "24 to 120" in the application as filed, it is concluded that the newly introduced limitation in the pending claims are not described in the specification as originally filed. Further, the specification does not provide adequate written description for the claimed isolated nucleic acids of 24-120 nucleotides in length having at least 70.9%, 79.2%, and 83.4% sequence identity to

SEQ ID NO:3588. There is no indication or suggestion that applicant possessed or contemplated making an isolated nucleic acid having at least 70.9%, 79.2%, or 83.4% sequence identity to SEQ ID NO:3588 at the time the application was originally filed, as evidenced by the fact that the sequence search results for SEQ ID NO:3588 within the recited sequence identity levels do not identify the instant application as containing the claimed nucleic acids with various sequence identity levels. Since there is no piece of disclosure in the specification that points to the specifically recited minimum level of sequence identity claimed in the instant case, the specification has failed to convey with reasonable clarity to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 23, and 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Mounts et al. (US 2007/0031850 A1, citation of record).

Note that the benefit of an earlier filing date is denied. See page 3 above.

The claims are drawn to an isolated nucleic acid of 24 to 120 nucleotides, comprising a sequence at least 79.2% identical to SEQ ID NO:3588.

Mounts et al. teach an isolated nucleic acid of 25 nucleotides in length comprising SEQ ID NO:273968 ("Db"), 20 nucleotides of which perfectly align with nucleotides of SEQ ID NO:3588 ("Qy") of the instant application as shown below, thereby rendering 80% sequence identity between SEQ ID NO:273968 of Mounts et al. and SEQ ID NO:3588 of the instant application.

```
Qy          2 CACCAGAATGCTAGTTTGTAGAG 24
              ||||||||  ||||  ||||||  ||
Db          2 CACCAGAAGGCTATTTTGTACAG 24
```

They also teach an isolated nucleic acid of 25 nucleotides in length comprising SEQ ID NO:273971 ("Db"), 20 nucleotides of which perfectly align with nucleotides of SEQ ID NO:3588 ("Qy") of the instant application as shown below, thereby rendering 80% sequence identity between SEQ ID NO:273968 of Mounts et al. and SEQ ID NO:3588 of the instant application.

```
Qy          2 CACCAGAATGCTAGTTTGTAGAG 24
              ||||||||  ||||  ||||||  ||
Db          1 CACCAGAAGGCTATTTTGTACAG 23
```

Accordingly, all of the claim limitations are taught by Mounts et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21, 23, 32-33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mounts et al. (US 2007/0031850 A1) as applied to claims 21, 23, and 32-33 above, and further in view of Paul et al. (*Nature Biotechnology,* 2002, 29:505-508, citation of record).

Claims 21, 23, and 32-33 are described above.

Claim 36 is directed to a vector comprising any of the nucleic acids of claims 21, 23, and 32-33.

Mounts et al. teach two nucleic acids of SEQ ID NO: 273968 and SEQ ID NO: 273971 that are 80% identical to SEQ ID NO:3588. Mounts et al. do not teach a vector comprising either SEQ ID NO:273968 or SEQ ID NO:273971.

Paul et al. teach a vector comprising an isolated nucleic acid, which allows long-term expression of the isolated nucleic acid in human cells and potentially in whole organisms. See entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a vector comprising either one of SEQ ID NO: 273968 and SEQ ID NO: 273971 of Mounts et al.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because Paul et al. teach that an isolated nucleic acid expressed from a vector is more stable and thus can be expressed in human cells for a longer period of time and potentially can be expressed in whole organisms. Since the technique and knowledge of inserting isolated nucleic acids into a vector were known and available in the art at the time the invention was made, the instantly claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner
Art Unit 1635